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10/560,539	06/19/2006	Andreas Lendlein	Q116798	6451

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
SCHUBERT, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
07/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/560,539	LENDLEIN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER SCHUBERT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amendment filed 6/04/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 and 4-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandrasekaran (US 2003/0153971).

1. Regarding claims 1, Chandrasekaran discloses a stent for use in a non-vascular or vascular field, the stent comprising a basic structure (10) made of a degradable metal (paragraph 0010 discloses stainless steel which Sirhan et al US 2003/0139801 discloses is a type of degradable metal in par 0022); and a biodegradable shape memory polymer (SMP) material selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks (col. 9, ln. 5-52 of US Patent No. 6,160,084 which is incorporated by reference in paragraph 63), and wherein the SMP material covers the basic structure (paragraph 30). Chandrasekaran discloses the basic structure comprises a metallic reinforcing component coated with a biodegradable polymer (paragraph 39), wherein the metallic reinforcing component is insufficient to maintain patency of the lumen after the biodegradable polymer has degraded (paragraph 10).

Regarding claim 4, Chandrasekaran discloses the stent comprises additional additives selected among x-ray contrast materials and medically effective compounds (paragraphs 48 and 58).

Regarding claim 5, Chandrasekaran discloses the SMP is selected from among the following: polymer networks, thermoplastic SMP materials, composite materials, and blends (col. 9, ln. 5-52 of US Patent No. 6,160,084 which is incorporated by reference in paragraph 63).

Regarding claim 6, Chandrasekaran discloses the SMP material is selected from among at least one of the SMP materials in which the SMP effect is induced thermally, is photo-induced, wherein the SMP is biocompatible, haemocompatible, and wherein the SMP reveals a particle free degredation behavior (paragraphs 60 and 63-65).

Regarding claim 7, Chandrasekaran discloses the network includes at least one of the following: caprolacton units and pentadecalacton units (col. 7, ln. 27-28 of US 6,160,084 which is incorporated by reference in paragraph 63).

Regarding claim 8, Chandrasekaran discloses the network consists of cross-linked caprolacton macromonomers (col. 7, ln. 27-28 of US 6,160,084 which is incorporated by reference in paragraph 63).

Regarding claims 9 and 10, Chandrasekaran discloses the stent comprises a surface coating that modifies haemocompatibility (paragraph 48).

Regarding claim 11, Chandrasekaran discloses a method of manufacturing biocompatible SMP materials comprising the processing of SMP material to a stent by

one of the following extrusion methods, coating methods, metal casting methods, and spinning and weaving methods (paragraph 42).

2.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 3 and 15-16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasekaran (US 2003/0153971) in view of Bolz et al. (US 6,287,332).

3. Regarding claim 3, Chandrasekaran discloses a stent for use in a non-vascular or vascular field, the stent comprising a basic structure (10) made of a degradable metal (paragraph 0010 discloses stainless steel which Sirhan et al US 2003/0139801 discloses is a type of degradable metal in par 0022); and a biodegradable shape memory polymer (SMP) material selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks (col. 9, ln. 5-52 of US Patent No. 6,160,084 which is incorporated by reference in paragraph 63), and wherein the SMP material covers the basic structure (paragraph 30) and the stent additionally comprises a surface coating that modifies hemocompatability (paragraph 48). Chandrasekaran discloses the basic structure comprises a metallic reinforcing component coated with a biodegradable polymer (paragraph 39), wherein the metallic reinforcing component is insufficient to maintain patency of the lumen after the

biodegradable polymer has degraded (paragraph 10), but fails to disclose the degradable metal includes one of the following: a magnesium alloy, pure magnesium, and a composite of magnesium or a magnesium alloy with biodegradable polymer.

Bolz et al. discloses a biodegradable metallic stent comprising a sodium-magnesium alloy (col. 3, ln. 11-17). Bolz et al. discloses that the biodegradable stent provides the mechanical properties of typical metal stents (col. 2, ln. 13-16).

It would have been obvious to one of ordinary skill in the art to substitute the metal reinforcing member of Chandrasekaran with reinforcing member comprising a a sodium-magnesium alloy in order to achieve the same predictable result of a metal reinforcing member that will not harm the vessel following the degradation of the polymer.

4. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasekaran (US 2003/0153971) in view Igaki (EP 1033145 A1).

Regarding claim 12, Chandrasekaran discloses a stent in which the change in shape is triggered by application of heat (paragraph 63), but fails to disclose at least one of a temperature controlled balloon catheter or a balloon catheter with an optical fiber for deploying the stent.

Igaki discloses a system, comprising a stent (1) of a biodegradable SMP material (paragraph 36), and a temperature controlled balloon catheter for applying heat to the stent to trigger expansion in the vessel (paragraphs 51-52).

It would have been obvious to one of ordinary skill in the art provide a temperature controlled balloon to deploy the biodegradable SMP stent of

Chandrasekaran since Igaki has disclosed that it is well known in the art to provide a temperature controlled balloon to apply heat to a biodegradable SMP stent to trigger expansion of the stent within the vessel.

Regarding claims 13 and 14, Chandrasekaran discloses a stent in which the change in shape is triggered by application of heat (paragraph 63), but fails to disclose method for implanting the stent comprising placing the stent onto at least one of a temperature controlled balloon catheter or a balloon catheter with an optical fiber for deploying the stent.

Igaki discloses a method for minimal invasive implantation of a stent, comprising the following steps: placing a stent of a biodegradable SMP material onto a temperature controlled balloon, wherein the SMP material has two shapes in the memory and wherein this material was programmed to two shapes, wherein the first shape, compared to a second shape, is a tubular shape with a larger diameter, inserting the stent to the desired position, wherein the SMP material exists in its second shape; heating the stent by inserting a heating medium into the catheter; activating the SMP effect to bring the stent into the first shape, and removing the balloon catheter (paragraphs 51-52). It would have been obvious to one of ordinary skill in the art to implant the biodegradable SMP stent of Chandrasekaran using the method of Igaki since Igaki has disclosed that it is well known in the art to provide a temperature controlled balloon to apply heat to a biodegradable SMP stent to trigger expansion of the stent within the vessel.

5.

6. Claims 1, 3-11, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasekaran (US 2003/0153971) in view of Bolz et al. (US 6,287,332).

Regarding claims 1, 3, and 15-16 Chandrasekaran discloses a stent for use in a non-vascular or vascular field, the stent comprising a basic structure (10) made of a metal (paragraph 38); and a biodegradable shape memory polymer (SMP) material selected from the group consisting of covalent polymer networks and covalent polymer interpenetrating networks (col. 9, ln. 5-52 of US Patent No. 6,160,084 which is incorporated by reference in paragraph 63), and wherein the SMP material covers the basic structure (paragraph 30) and the stent additionally comprises a surface coating that modifies hemocompatibility (Par 48). Chandrasekaran discloses the basic structure comprises a metallic reinforcing component coated with a biodegradable polymer (paragraph 39), wherein the metallic reinforcing component is insufficient to maintain patency of the lumen after the biodegradable polymer has degraded (paragraph 10). Chandrasekaran discloses the claimed invention except for the basic structure comprising a degradable metal.

Bolz et al. discloses a biodegradable metallic stent comprising a sodium-magnesium alloy (col. 3, ln. 11-17). Bolz et al. discloses that the biodegradable stent provides the mechanical properties of typical metal stents (col. 2, ln. 13-16). It would have been obvious to one of ordinary skill in the art to substitute the metal reinforcing member of Chandrasekaran with reinforcing member comprising a degradable metal such as a sodium-magnesium alloy in order to achieve the same predictable result of a

metal reinforcing member that will not harm the vessel following the degradation of the polymer.

Regarding claim 4, Chandrasekaran discloses the stent comprises additional additives selected among x-ray contrast materials and medically effective compounds (paragraphs 48 and 58).

Regarding claim 5, Chandrasekaran discloses the SMP is selected from among the following: polymer networks, thermoplastic SMP materials, composite materials, and blends (col. 9, ln. 5-52 of US Patent No. 6,160,084 which is incorporated by reference in paragraph 63).

Regarding claim 6, Chandrasekaran discloses the SMP material is selected from among at least one of the SMP materials in which the SMP effect is induced thermally, is photo-induced, wherein the SMP is biocompatible, haemocompatible, and wherein the SMP reveals a particle free degredation behavior (paragraphs 60 and 63-65).

Regarding claim 7, Chandrasekaran discloses the network includes at least one of the following: caprolacton units and pentadecalacton units (col. 7, ln. 27-28 of US 6,160,084 which is incorporated by reference in paragraph 63).

Regarding claim 8, Chandrasekaran discloses the network consists of cross-linked caprolacton macromonomers (col. 7, ln. 27-28 of US 6,160,084 which is incorporated by reference in paragraph 63).

Regarding claims 9 and 10, Chandrasekaran discloses the stent comprises a surface coating that modifies haemocompatibility (paragraph 48).

Regarding claim 11, Chandrasekaran discloses a method of manufacturing biocompatible SMP materials comprising the processing of SMP material to a stent by one of the following extrusion methods, coating methods, metal casting methods, and spinning and weaving methods (paragraph 42).

7. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrasekaran (US 2003/0153971) in view of Bolz et al. (US 6,287,332) as applied to claim 1 above and further in view Igaki (EP 1033145 A1).

Regarding claim 12, Chandrasekaran discloses a stent in which the change in shape is triggered by application of heat (paragraph 63), but fails to disclose at least one of a temperature controlled balloon catheter or a balloon catheter with an optical fiber for deploying the stent.

Igaki discloses a system, comprising a stent (1) of a biodegradable SMP material (paragraph 36), and a temperature controlled balloon catheter for applying heat to the stent to trigger expansion in the vessel (paragraphs 51-52).

It would have been obvious to one of ordinary skill in the art provide a temperature controlled balloon to deploy the biodegradable SMP stent of Chandrasekaran since Igaki has disclosed that it is well known in the art to provide a temperature controlled balloon to apply heat to a biodegradable SMP stent to trigger expansion of the stent within the vessel.

Regarding claims 13 and 14, Chandrasekaran discloses a stent in which the change in shape is triggered by application of heat (paragraph 63), but fails to disclose method for implanting the stent comprising placing the stent onto at least one of a

temperature controlled balloon catheter or a balloon catheter with an optical fiber for deploying the stent.

Igaki discloses a method for minimal invasive implantation of a stent, comprising the following steps: placing a stent of a biodegradable SMP material onto a temperature controlled balloon, wherein the SMP material has two shapes in the memory and wherein this material was programmed to two shapes, wherein the first shape, compared to a second shape, is a tubular shape with a larger diameter, inserting the stent to the desired position, wherein the SMP material exists in its second shape; heating the stent by inserting a heating medium into the catheter; activating the SMP effect to bring the stent into the first shape, and removing the balloon catheter (paragraphs 51-52). It would have been obvious to one of ordinary skill in the art to implant the biodegradable SMP stent of Chandrasekaran using the method of Igaki since Igaki has disclosed that it is well known in the art to provide a temperature controlled balloon to apply heat to a biodegradable SMP stent to trigger expansion of the stent within the vessel.

Response to Arguments

1. Langer has been cited on the PTO-892 as requested.

2. Applicant's arguments filed 6/08/2010 have been fully considered but they are not persuasive.

3. Chandrasekaran does disclose a variety of metals that can be used as the core of the stent including stainless steel (par 0010). Furthermore, Sirhan et al US

2003/0139801 discloses that stainless steel is an example of a metal that is degradable within the body ("Examples of metallic material include metals or alloys degradable in the corporeal body, such as stainless steel"). In view of this teaching reference, Chandrasekaran does disclose a type of metal that may be used which is a degradable metal.

4. Furthermore, Sirhan et al discloses "partially biodegradable material selected from the group consisting of polymeric material, metallic materials . . " in paragraph 10. This teaches that degradable metals and degradable polymers may be interchanged. Furthermore, Chandrasekaran discloses that multiple layers of degradable polymer with different degradation characteristics may be utilized (Par 0040-0041). The disclosure of Chandrasekaran in view of the teachings of Sirhan provide ample reasoning for substituting a degradable metal for at least one of the layers of degradable polymer.

5. In addition, since the metallic reinforcing component of Chandrasekaran is not intended to maintain the patency of the lumen (Abstract), substituting a specific type of degradable metal for the metallic reinforcing component would be obvious since both would serve the same purpose, which is to initially support the lumen in conjunction with the outer degradable polymer layer(s), and then later fail to support the lumen.

6. Examiner believes there are multiple reasons for substituting the degradable metal of Bolz et al. (US 6,287,332) for the metallic reinforcing component of Chandrasekaran. Examiner also believes that Chandrasekaran discloses a useable degradable metal as a type of metallic reinforcing component in the disclosure of stainless steel.

7. Applicant points out that Chandrasekaran emphasizes the importance of a non-degradable basic structure. Examiner asks the applicant to clearly point out this reference. The last two sentences as pointed out by the applicant read as follows, "Upon in vivo biodegradation of the polymeric material, the remaining flexible metallic framework of the stent will be advantageously less bulky and have a smaller surface area in direct contact with the lumen walls. At such point, the remaining flexible metallic framework of the stent will be compliant with the contacting lumen walls and be less likely to cause damage or injury thereto if left implanted indefinitely." The use of a degradable metal framework is consistent with every part of the statements the applicant points out. It would be less bulky, have smaller surface area in contact with lumen walls, be compliant with contacting lumen walls, and be less likely to cause damage or injury if left implanted indefinitely. Furthermore, Chandrasekaran notes that the flexible metal framework may be passivated to enhance biostability. There is no disclosure that the metallic reinforcing framework of Chandrasekaran must be non-degradable, or that it must be passivated. The disclosure does not teach away from a degradable metal.

8. Applicant notes that there is a clear teaching of preference for the thermoplastic polymers over the thermoset polymers. Langer may have noted a preference, but Langer also noted the use of thermoset polymers. A prior art's preference of one material over another is not sufficient to overcome the disclosed use of both materials.

9. Applicant notes that various additional features in other claims such as 3 and 10 provide additional distinctions over the cited art reference. Although applicant has not

noted the specifics of these distinctions, examiner asserts it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER SCHUBERT whose telephone number is (571)270-1656. The examiner can normally be reached on M-F 7:30-5pm ESD.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 5712724713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
01/27/2010

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734